

FR
CWS
SUB G2
CWS

conferring sequence with at least 50% homology with the sunflower orf 522 sequence, wherein said male-sterility-conferring sequence comprising polynucleotide sequences shown in SEQ ID NOS: 1 and 2.

REMARKS

In the August 7th Advisory Action, Examiner Kruse noted that the Applicants' response of July 12, 2002, was non-responsive because it does not incorporate the content of the amendment, arguments and other issues filed on May 13, 2002. In addition, Applicants' reply to the June 25th Advisory Action was non-responsive because the clean copy of twice amended claim 12 did not incorporate the changes of the marked-up copy of the same claim as shown on page 7 of the response. Accordingly, Applicants herewith submit a complete response to the final Office Action of January 14, 2002.

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons, which follow.

Claims 12-19 are pending in the application. The claims are amended to overcome the indefiniteness rejections and to clearly set forth the nature of the claimed invention. Support for the amendments is found throughout the entire specification, specifically at page 4, lines 24-25. Non-elected claims 13, 14, and 19, are cancelled without prejudice to Applicants' option to file a divisional application with respect to the subject matter of these claims. Therefore, claims 12 and 15-18 are presented for reconsideration in view of the remarks below. The amendments do not go beyond the original disclosure of the application.

Rejection Under 35 U.S.C. § 112, First Paragraph

I. Written Description Requirement

The Examiner has maintained the indefiniteness rejection of claims 12 and 15-18 and asserts that "the claims are not so limited to chicory plants" or "to a sunflower sequence" but rather they are directed to "a recombinant plant genome comprising a male sterility-conferring sequence with at least 50% homology with the sunflower orf 522 sequence...SEQ ID NOS:1 and 2." Applicants respectfully traverse this rejection.

The Examiner alleges that it is "unclear" from the specification "how one of skill in the art would have made or identified the male-sterility conferring sequence with at least 50% homology to the sunflower orf 522 sequence without undue trial and error experimentation, if the Applicants themselves fail to understand the mechanism by which the sunflower orf 522 sequence confers male sterility in a plant." As stated and argued previously, "an applicant need not understand the theory or scientific principle underlying his invention to comply with section 112." *In re Isaacs*, 146 U.S.P.Q. 193, 197 (CCPA 1965) (See Applicants' Reply to the Office Action dated June 19, 2001, at page 2, last full paragraph, line 9 to page 3, lines 1-2).

The Examiner further cites *In re Fiers* to support his above allegation that "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it; what is required is a description of the DNA itself." Applicants submit that the statement in *Fiers* is irrelevant to the present application. In *Fiers*, the appellants' specification lacked adequate written description of the claimed DNA and "d[id] not even demonstrate that the disclosed method actually leads to the DNA." Rather, it "disclose[d] a clone that might be used to obtain mRNA coding for β -IF." The specification provides an adequate written description of an identifiable physical or chemical property of the claimed plant recombinant genome, that is, a male sterile phenotype. In addition, it comprises a sunflower orf 522 sequence or a male sterility conferring sequence with at least 50% homology to the sunflower orf 522 sequence (see specification at pages 2-3).

Furthermore, contrary to *Fiers*, the specification at pages 7-9, Example 2, demonstrates, via PCR analysis, the presence of a 350-bp orf 522 fragment in male sterile chicory plants and its absence in all normal chicory plants.

Accordingly, the claims are not limited to the chicory plants or to a sunflower sequence. However, for the purpose of expediting prosecution, claims 12 and 18 are amended to recite "a plant recombinant genome that comprises a male-sterility conferring sequence with at least 50% homology with the sunflower orf 522 sequence and comprises polynucleotide sequences of SEQ ID NOS:1 and 2."

In light of the above remarks and amendments, Applicants earnestly request reconsideration and withdrawal of the rejection.

II. Enablement Requirement

The Examiner rejects claims 12 and 15-18 on the basis that the specification "does not reasonably provide enablement for any recombinant plant genome comprising a male sterility...." Applicants respectfully traverse this rejection.

With respect to claim 12, the Examiner alleges that the "Applicant has not taught a recombinant plant genome other than that produced by protoplast fusion with a chicory derived protoplast." It is sufficient to provide one representative working example since the Applicants are not required to exemplify every embodiment of the claimed invention. Moreover, a "failure to disclose other methods by which the claimed invention may be made does not render a claim invalid under Section 112." *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1533, 3 U.S.P.Q.2d 1737, 1743 (Fed. Cir.), cert. Denied, 484 U.S. 954 (1987).

With respect to claims 15-18, the Examiner alleges that the "Applicant has not taught how to identify within the sunflower orf 522 sequence what is critical in conferring a male-sterile phenotype...and has not taught how to make or identify a male sterility-conferring sequence with at least 50% homology with the sunflower orf 22 sequence...as broadly claimed." A disclosure of the mechanism by which orf 522 confers sterility is unnecessary to comply with the enablement requirement of section 112. As stated above, "an applicant need not understand the theory or scientific principle underlying his invention to comply with section 112." *In re Isaacs*, 146 U.S.P.Q. 193, 197 (CCPA 1965). The specification, at pages 7-9, Example 2, describes how one of ordinary skill can make or identify a male-sterility-conferring sequence with at least 50% homology with the sunflower orf 522 sequence. More specifically, the specification discloses, via PCR analysis, the presence of a 350-bp orf 522 fragment in male sterile chicory plants and its absence in all normal chicory plants.

To expedite prosecution, however, claims 12 and 18 are amended to more clearly set forth the claimed invention. In view of the claim revisions and above arguments, Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection Under 35 U.S.C. § 103

Claims 12 and 15-18 remain rejected under section 103, as being unpatentable over Rambaud (1994), in view of Rambaud (1993) and Laver (1991). The Examiner

contends that Laver, at page 188, Figure 3, teaches SEQ ID NOS:1 and 2 and allegedly concludes that "it would have been obvious to use Laver's teachings to modify the teachings of Rambaud at the time of the Applicant's invention." Applicants respectfully traverse this rejection.

At the outset, the Examiner has failed to establish a *prima facie* case of obviousness with respect to the claimed invention. He must show all of the recited claim elements in the combination of references that underscore the rejection. When combining elements to make out a *prima facie* case of obviousness, that is, the Examiner is obliged to show by reference to specific evidence in the cited references that there was (i) a suggestion to make the combination and (ii) a reasonable expectation that the combination would succeed. Both suggestion and reasonable expectation must be found within the prior art, and not be gleaned from Applicants' disclosure. *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991); *In re Dow Chemical Co.*, 5 U.S.P.Q.2d 1529, 1531 (Fed Cir. 1988).

Rambaud (1994), at page 67(7), had indicated that their results were preliminary and did not allow them to determine whether the orf 522 gene was responsible for the CMS trait in chicory. As argued previously, "Rambaud (1994) only invites further experimentation to try to establish the identity of the DNA sequence(s) that conferred CMS. Such an invitation provides no more than 'general guidance as to the particular form of the invention or how to achieve it.' *In re O'Farrell*, 7 U.S.P.Q.2d 1673, 1681, (Fed. Cir. 1988); see generally M.P.E.P. § 2145." (Applicant's Reply to the Office Action dated June 19, 2001, page 6, Section 4).

In addition, Rambaud (1993), at page 351, column 1, fourth paragraph, lines 14-21, clearly states that:

"We were unable to determine whether the appearance of sterility in chicory is due to a transfer of the sunflower gene responsible for this characteristic, as suggested by Kohler *et al.*(1991) and by Laver *et al.* (1991), or whether the fusion process has given rise to a new chimeric gene which would induce a new type of male sterility specific to chicory."

Accordingly, one of ordinary skill in the art would have no motivation to combine the secondary references relating to fusion techniques and orf 522 gene, without a reasonable degree of certainty. Moreover, the Examiner has not provided any reasoning why these references can be combined. The level of skill in the art alone

cannot be relied upon to provide the suggestion to combine references. *Al-Site Corp. v. VSI Int'l. Inc.*, 174 F.3d 1308, 50 U.S.P.Q.2d 1161 (Fed Cir. 1999).

The Examiner did not err in stating that Laver discloses the sequences that comprise SEQ ID NOS:1 and 2. Laver, however, fails explicitly or implicitly to suggest use of the sequences comprising SEQ ID NOS:1 and 2 for modifying Rambaud's teaching to make or practice the claimed invention. There is nothing in Laver that directs an artisan to choose these particular regions of the *atpA* gene for use in making a male sterile chicory plant as presently claimed. Even if Laver provides the suggestion to combine Rambaud's teachings, there is no reasonable expectation of success, as clearly concluded in Rambaud (1994) and Rambaud (1993). These references, at best, would have motivated the artisan to try to make the claimed invention. However, an "obvious to try" standard is an improper basis for applying an obviousness rejection.

Accordingly, the Examiner has failed to make a case of *prima facie* obviousness, and as a result of these deficiencies, it is respectfully requested that the above rejection be withdrawn.

CONCLUSION

In view of the following remarks, Applicants believe the present application is now in condition for allowance. An early notice in this regard is earnestly solicited. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. § 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date

Sept. 12, 2002

By

Stephen B. Maebius

FOLEY & LARDNER

Customer Number: 22428



22428

PATENT TRADEMARK OFFICE

Telephone: (202) 672-5569

Facsimile: (202) 672-5399

Stephen B. Maebius

Attorney for Applicants

Registration No. 35,264

Version with markings showing changes made

12. (Thrice Amended) A recombinant plant genome comprising at least one chicory gene and [a nucleotide sequence conferring male sterility borne by a sunflower orf 522 sequence or by] a male-sterility-conferring sequence with at least 50% homology with the sunflower orf 522 sequence, wherein [said sunflower orf 522 sequence or] said male-sterility-conferring sequence comprises polynucleotide sequences [having the sequence] shown in SEQ ID NOS:1 and 2.

18. (Thrice Amended) A method of producing a plant of the chicory genus or reproducing material of a plant of the chicory genus exhibiting cytoplasmic male sterility, comprising integrating into a cell genome of the plant a [nucleotide sequence conferring male sterility borne by a sunflower orf 522 sequence or by a] male-sterility-conferring sequence with at least 50% homology with the sunflower orf 522 sequence, wherein [said sunflower orf 522 sequence or] said male-sterility-conferring sequence comprises polynucleotide sequences [having the sequence] shown in SEQ ID NOS:1 and 2.